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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,705	09/25/2003	Hao Chen	6695.0004-01	6343

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CALIPER LIFE SCIENCES, INC.
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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,705

Applicant(s)

CHEN ET AL.

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/14/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 9-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/23/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

APPLICANT'S ELECTION

Applicant's election without traverse of Group I (Claims 1-8) in the reply filed on 04/14/2006 is acknowledged. Applicant's election without traverse of Specie A ("toxicity" as recited in instant claim 5) is acknowledged. Claims 9-37 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim.

CLAIMS UNDER EXAMINATION

Claims herein under examination are Claims 1-8 as they read on the elected species. An action on the merits follows.

ABSTRACT

The abstract of the disclosure is objected to because it exceeds 150 words. Correction is required. See MPEP § 608.01(b).

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement filed 11/23/2004 has been considered in full.

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. Claims 1-8 are directed to a method of “drug discovery and development comprising using one or more databases comprising chemical and biological interaction data and one or more computer-based data analysis programs” does not recite either a physical transformation of matter nor a practical application. Claim 1 recites a database comprising data and computer-based data analysis programs to “identify” compounds. The specification does not define the identification of compounds such that it is necessarily a physical step. A database is nonfunctional descriptive material and is not statutory subject matter. A program without any functionality to perform the instructions is not statutory subject matter. Therefore, the combination of a database and a program does not render either statutory. Processes may be statutory where they recite a concrete, tangible, and useful result (i.e. a practical application). However, no actual, concrete result is recited in the claims, nor is any useful result “produced” in a tangible form useful to one skilled in the art. For the reasons set forth above, the claims are not statutory. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, Annex IV, Nov. 22, 2005.

Claims 1-8 provide for the use of one or more databases comprising chemical and

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biological interaction data and one or more computer-based data analysis programs, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 recite the limitation "using one or more databases comprising chemical and biological interaction data and one or more computer-based data analysis programs." It is unclear what step or steps are intended to be encompassed by the "using" limitation recited in claims 1 and 5. Clarification is requested.

Claims 2 and 6 recite the limitation "identifying additional applications." As no "applications" or "uses" were identified in claim 1 or claim 5, it is unclear what is meant by

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"additional" applications. Clarification is requested. It is noted that the parent claims are directed to identifying "compounds" with a desired activity.

Claims 4 and 8 recite the limitation "compounds that display patterns of activity". As the specification does not define or fully describe "patterns of activity", it is unclear as to the intended meaning of compounds that display "patterns of activity", as this could be interpreted to be something that is physically displayed or merely a characteristic property of the compound. Clarification is requested.

Claim 5 recites the limitation "reduced" activity. As the specification does not define or fully and completely describe "reduced activity," such that one would know what the activity is "reduced" relative to, it is unclear as to the metes and bounds intended by applicant for the claimed "reduced activity." Clarification is requested.

Claim 5 recites the limitation "or other properties...manifested by compounds being developed to treat the disease state associated with the drug discovery." It is unclear in what way this limitation further limits the claimed method, and exactly what is being limited. Clarification is being requested.

Claim 7 recites the limitation "multiple targets relevant to the treatment of a specific disease state." As the parent claim is directed to a method of identifying compounds, it is unclear what the "multiple targets" as recited in claim 7 are targets for (i.e. a receptor for a drug, a compound, a cell, or something else). Clarification is requested.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102 (b) as being anticipated by Lawrence et al. (Proteins: Structure, Function, and Genetics, 1992, 12, p.31-41).

Lawrence et al. teach a search algorithm for finding novel therapeutic agents capable of binding proteins of known 3-D structure [Abstract], as in instant claims 1 and 2. More specifically, Lawrence et al. teach the following aspects of the instant invention:

- Databases comprising chemical and crystallographic connectivity (i.e. biological interaction) data of small organic molecules [Abstract and p.37, Col. 2, ¶ 2], as in instant claim 1.
- Probe/protein interaction-energy map data generated [p.32, Col. 2 ¶ 4], which is also a teaching for biological interaction data as in instant claim 1.
- GRID program determines favorable interaction positions (i.e. molecular target sites) in the binding site of the protein [p.32, Methods, ¶ 1], and identification of sialic acid binding site and a number of potential sialic acid-protein interactions [p.37, Col. 2, ¶ 2], which is a teaching for two or more molecular targets as in instant claims 1, 3, and 7.

- GRID examines the chemical structure of candidate molecule [Fig. 1] and suggests chemical changes to candidate molecules that enhance binding with a target protein [p.35, col. 2, Chemical Substitutions], which correlates to identifying additional applications and uses of known compounds, as in instant claims 2 and 6.
- GRID identifies a number of new ligands to the protein associated with a mutant influenza virus [Table 1], which correlates to identification of multiple candidate compounds associated with treatment of a disease state as in instant claims 1 and 3.
- GRID selects candidates based on favorable geometric and chemical interaction with the protein binding site [p. 31, col. 2, ¶ 2], which correlates to *in silico* identification of compounds based on “patterns of activity” as in instant claim 4 and “desired activity” as in instant claim 8.
- CLIX program searches for candidate molecules from a set (L) generated by excluding molecules containing known toxic elements [p.33, Col. 1, ¶ 1 and ¶ 2], which is a teaching for selection of compounds associated with toxicity as in instant claim 5.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner
Art Unit 1631
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MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
6/26/06